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Atty. Dkt. No. 029318-0107

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

3

Applicant: Bosch et al.

Title: STERILE FILTERED
NANOPARTICULATE
FORMULATIONS OF
BUDESONIDE AND
BECLOMETHASONE HAVING
TYLOXAPOL AS A SURFACE
STABILIZER

Appl. No.: 10/035,324

Filing Date: 01/04/2002

Examiner: Not Yet Assigned

Art Unit: Not Yet Assigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
Box PATENT APPLICATION
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO-SB08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document

which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the filing date of the application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-SB08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

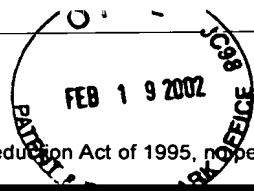
Respectfully submitted,

Date February 19, 2002

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Substitute for form 1493/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Date Submitted: February 17, 2002

(use as many sheets as necessary)

Sheet 1 of 3

Complete if Known

Application Number	10/035,324
Filing Date	01/04/2002
First Named Inventor	H. William Bosch
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	029318-0107

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	5,145,684		Liversidge et al.	09/08/1992	
	A2	5,518,187		Bruno et al.	05/21/1996	
	A3	5,862,999		Czekai, et al.	01/26/1999	
	A4	5,718,388		Czekai et al.	02/17/1998	
	A5	5,510,118		Bosch, et al.	04/23/1996	
	A6	5,298,262		Na et al.	03/29/1994	
	A7	5,302,401		Liversidge et al.	04/12/1994	
	A8	5,318,767		Liversidge et al.	06/07/1994	
	A9	5,326,552		Na et al.	07/05/1994	
	A10	5,328,404		Bacon	07/12/1994	
	A11	5,336,507		Na et al.	08/09/1994	
	A12	5,340,564		Illig et al.	08/23/1994	
	A13	5,346,702		Na et al.	09/13/1994	
	A14	5,349,957		Yudelson	09/27/1994	
	A15	5,352,459		Hollister et al.	10/04/1994	
	A16	5,399,363		Liversidge et al.	05/21/1995	
	A17	5,494,683		Liversidge et al.	02/27/1996	
	A18	5,401,492		Kellar et al.	03/28/1995	
	A19	5,429,824		June	07/04/1995	
	A20	5,447,710		Na et al.	09/05/1995	
	A21	5,451,393		Liversidge et al.	09/19/1995	
	A22	5,466,440		Ruddy et al.	11/14/1995	
	A23	5,470,583		Na et al.	11/28/1995	
	A24	5,472,683		Illig	12/05/1995	
	A25	5,500,204		Osifo	03/19/1996	
	A26	5,521,218		Osifo	05/28/1996	
	A27	5,525,328		Bacon, et al.	06/11/1996	
	A28	5,543,133		Swanson et al.	08/06/1996	
	A29	5,552,160		Liversidge et al.	09/03/1996	
	A30	5,560,931		Eickhoff et al.	10/01/1996	
	A31	5,565,188		Wong et al.	10/15/1996	
	A32	5,569,448		Wong et al.	10/29/1996	
	A33	5,571,536		Eickhoff et al.	11/05/1996	
	A34	5,573,749		Illig	11/12/1996	
	A35	5,573,750		Singh	11/12/1996	
	A36	5,573,783		Desieno et al.	11/12/1996	
	A37	5,580,579		Ruddy et al.	12/03/1996	
	A38	5,585,108		Ruddy et al.	12/17/1996	
	A39	5,587,143		Wong	12/24/1996	
	A40	5,591,456		Franson et al.	01/07/1997	
	A41	5,593,657		Ruddy et al.	01/04/1997	
	A42	5,622,938		Wong	04/22/1997	
	A43	5,628,981		Liversidge et al.	05/13/1997	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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FEB 19 2002

PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031
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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

Date Submitted: February 17, 2002

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Sheet 2 of 3

Complete if Known

Application Number	10/035,324
Filing Date	01/04/2002
First Named Inventor	H. William Bosch
Group Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
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		U.S. Patent Document			
A44	5,643,552		Illig	07/01/1997	
A45	5,718,388		Czekai et al	02/17/1998	
A46	5,718,919		Ruddy et al	02/17/1998	
A47	5,747,001		Wiedmann et al	05/05/1998	
A48	5,834,025		de Garavilla et al	11/10/1998	
A49	6,045,829		Liversidge et al	04/04/2000	
A50	6,068,858		Liversidge et al	05/30/2000	
A51	6,153,225		Lee et al	11/28/2000	
A52	6,165,506		Jain et al	12/26/2000	
A53	6,221,400 B1		Liversidge, et al	04/24/2001	
A54	6,264,922 B1		Wood, et al	07/24/2001	
A55	6,267,989 B1		Liversidge et al	07/31/2001	
A56	6,270,806 B1		Liversidge et al	08/07/2001	
A57	4,783,484		Violante et al	11/08/1988	
A58	4,826,689		Violante et al	05/02/1989	
A59	4,997,454		Violante et al	05/05/1991	
A60	5,741,522		Violante et al	04/21/1998	
A61	5,776,496		Violante et al	07/07/1998	
A62	4,826,821		Clements	05/02/1989	
A63	3,272,700		Shupe	09/13/1966	
A64	5,662,883		Bagchi et al	09/02/1997	
A65	5,560,932		Bagchi et al	10/01/1996	
A66	5,534,270		De Castro	07/09/1996	
A67	5,091,187		Haynes	02/25/1992	
A68	5,091,188		Haynes	02/25/1992	
A69	4,851,421		Iwasaki et al	07/25/1989	
A70	4,540,602		Motoyama et al	09/10/1985	
A71	4,904,668		Kondo et al	02/27/1990	
A72	5,002,952		Kondo et al	03/26/1991	
A73	5,098,907		Kondo et al	03/24/1992	
A74	5,264,213		Shibahara et al	11/23/1993	
A75	4,727,077		Haga et al	02/23/1988	
A77	4,983,605		Kondo et al	01/08/1991	

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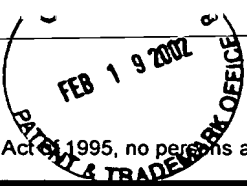
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴ Kind Code ⁵ (if known)				
	A78		0 262 560 A2	Ishihara Sangyo Kaisha Ltd	09/22/1987		Y
	A79		0 602 702 A1	Sterling Winthrop Inc.	06/22/1994		Y
	A80		GB 2 237 510 A	Danbiosyst UK Limited	05/08/1991		Y
	A81		WO 91/16038	Platz	10/31/1991		Y
	A82		DE 4327 063 A1	Westesen, et al.	02/16/1995		Y
	A83		WO 94/20072	Westesen, et al	09/15/1994		Y

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		Filing Date	01/04/2002
		First Named Inventor	H. William Bosch
		Group Art Unit	Not Yet Assigned
		Examiner Name	Not Yet Assigned
		Attorney Docket Number	029318-0107

Sheet	3	of	3
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		Office ³	Number ⁴	Kind Code ⁵ (if known)		
	A84		WO 92/08446		Taylor, et al	05/29/1992

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A85	William E. Serafin, "Therapeutic compounds Used in the Treatment of Asthma", <i>Goodman and Gilman's: The Pharmacological Basis of Therapeutics, Ninth Edition</i> 659-682 (J.G. Hardman et al., eds., McGraw Hill 1996)	Y
	A86	Kondo et al., "Improved Oral Absorption of Enteric Coprecipitates of a Poorly Soluble Drug," <i>J. Pharm. Sciences</i> , 83(4):566-570 (1994)	Y
	A87	Kondo, et al., "Improved Oral Absorption of a Poorly Water-Soluble Drug, HO-221, by Wet-Bead Milling Producing Particles in Submicron Region," <i>Chem. Pharm. Bull.</i> , 41(4):737-740 (1993)	Y
	A88	Kondo, et al., "Pharmacokinetics of a Micronized, Poorly Water-Soluble Drug, HO-221, in Experimental Animals," <i>Biol. Pharm. Bull.</i> , 16(8):796-800 (1993)	Y

Examiner Signature		Date Considered	
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